

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P11152WO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/000451	International filing date (day/month/year) 21.01.2004	Priority date (day/month/year) 21.01.2003
International Patent Classification (IPC) or national classification and IPC A61B 17/00, 17/12, 17/22		
Applicant PFM PRODUKTE FÜR DIE MEDIZIN AKTIENGESELLSCHAFT		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>10</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table><tr><td><input checked="" type="checkbox"/></td><td>Box No. I</td><td>Basis of the report</td></tr><tr><td><input type="checkbox"/></td><td>Box No. II</td><td>Priority</td></tr><tr><td><input type="checkbox"/></td><td>Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. VIII</td><td>Certain observations on the international application</td></tr></table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report																								
Name and mailing address of the IPEA/	Authorized officer																								
Facsimile No.	Telephone No.																								

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-54 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-37 _____ received by this Authority on 08.02.2005 with the letter of 08.02.2005
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/18 - 18/18 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. IV

Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted the claims nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:

See Supplemental Box.

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-27, 36, 37

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	<u>1-27, 36, 37</u>	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	<u>1-27, 36, 37</u>	NO
Industrial applicability (IA)	Claims	<u>1-27, 36, 37</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)**1. INDEPENDENT CLAIM 1**

1.1 The application fails to meet the requirements of PCT Article 33(1) because the subject matter of claims 1 to 27, 36 and 37 does not involve an inventive step (PCT Article 33(3)).

Expandable implantable devices with a support structure consisting of a single wiry element formed by interlaced winding in the manner of a woven fabric or net are generally known in the prior art.

1.2 **US-A-5 876 445** (document **D1**), for example, discloses the following:

An implantable device (see figure 4a) for use in the human body for closing or partially closing lumens (see column 14, lines 17 to 31) or for creating a defined connecting opening between lumens (see column 12, line 56 to column 13, line 17), with a support structure which in a first operating condition has a large ratio of length to lateral expansion along an axis, and in a second operating condition has a smaller ratio of length to lateral expansion along the axis, the support structure being formed from a single wiry element (see column 8, lines 30 to 31) by interlaced winding and/or

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

twisting and/or interweaving in the manner of a woven fabric and/or laid scrim and/or net; wherein the proximal and/or distal section (see column 13, lines 24 to 26) is conical or trumpet-shaped in the secondary form (see column 13, lines 1 to 17).

- 1.3 For a person skilled in the art it would be a routine procedure to make the proximal and/or distal section flat in order to (for example) improve the adhesion of the device to the walls. See, for example, figure 1 in **WO-A-98/47430** (document D2).

The subject matter of claim 1 therefore does not involve an inventive step.

2. INDEPENDENT CLAIM 36

- 2.1 The claimed process of winding and annealing a basic winding form is generally known (see, for example, D1, column 12, lines 56 to 57). For a person skilled in the art it is also obvious that more than one annealing step can be used in order to improve the material properties. The subject matter of claim 36 therefore does not involve an inventive step.

3. DEPENDENT CLAIMS 2-27 AND 37

Claims 2 to 27 and 37 do not contain any features that meet the PCT requirements in respect of novelty or inventive step when combined with the features of any of the back-referenced claims. The features of these claims relate merely to forms or coatings of the structure of the implantable device, all of which are already known from the prior art (see also the documents cited in the search report).

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Box No. VIII **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 25 is inconsistent with claim 1. The implantable device cannot consist both of a wiry element and of a laser-cut tube.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box IV**Lack of unity of invention**

The different groups of inventions are as follows:

1. Claims 1-27, 36 and 37: implantable device with a support structure composed of a single wiry element, and a manufacturing process.
2. Claims 28-35: placement system for an implantable device, with an advancing element and with a connecting device or retaining wire for connecting the proximal end of an implantable device.

These inventions or groups of inventions are not so linked as to form a single general inventive concept (PCT Rule 13.1). The reasons for this are as follows:

The only feature which is common to claims 1 and 28 or 32 is the fact that claim 1 claims an implantable device consisting of a wiry element and independent claims 28 and 32 claim placement systems for such implantable devices.

Wiry implantable devices are already known. Since these common "features" are already known they cannot be regarded as "special technical features" as required by PCT Rule 13.2.

The (potential) "special technical features" of the first invention relate to the fact that the support structure of the device is formed from a single element by interweaving in the manner of a woven fabric.

Supplemental Box

The (potential) "special technical features" of the second invention relate to the fact that the placement system is provided with a connecting device or retaining wire for connecting the proximal end of the implantable device.

Since there is no technical relation between these groups of claims, and since they solve different problems, there is a lack of unity.